

PROSKAUER ROSE LLP

Judson L. Hand (JH-1189)
One Newark Center, 18th Floor
Newark, NJ 07102
973-274-3200

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Advanced Research Centre

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUN PHARMACEUTICAL INDUSTRIES)
LTD. and SUN PHARMACEUTICAL)
ADVANCED RESEARCH CENTRE,)
)
Plaintiffs,)
v.) Civil Action No.: _____
)
ALTANA PHARMA AG and WYETH,)
)
Defendants.)
)
)

**COMPLAINT FOR DECLARATORY JUDGMENT
OF PATENT INVALIDITY**

Plaintiffs, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Advanced Research Centre (hereinafter collectively "Sun"), by their attorneys, for their Complaint allege as follows:

THE PARTIES

1. Sun Pharmaceutical Industries Ltd. is a public limited liability company incorporated and existing under the laws of the State of India, and has a principal place of business located at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

2. Sun Pharmaceutical Advanced Research Centre is a division of Sun Pharmaceutical Industries Ltd. and is located at NIMA Compound, Near Pratham Enclave, Tandalja Road, Baroda 390020, India.

3. Upon information and belief, Altana Pharma AG (hereinafter "Altana") is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

4. Upon information and belief, Wyeth is a Delaware corporation with its headquarters located at Five Giralta Farms, Madison, New Jersey 07940.

JURISDICTION AND VENUE

5. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Food, Drug, and Cosmetic Act of the United States, 21 U.S.C. § 355(j). Jurisdiction and venue are proper under 28 U.S.C. §§ 1331, 1338(a), 1391, 2201, 2202 and 21 U.S.C. § 355(j).

6. Upon information and belief, Altana directly or indirectly sells various products and conducts business throughout the United States including in this District.

7. Upon information and belief, Wyeth directly or indirectly sells various products and conducts business throughout the United States including in this District.

FACTUAL BACKGROUND

8. Upon information and belief, Wyeth Pharmaceuticals, Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application No. 20-987 by which the U.S. Food and Drug Administration granted Wyeth approval to market 20 mg and 40 mg delayed-release tablets containing pantoprazole sodium as the active ingredient in the United States. Upon

information and belief, Wyeth and Altana co-promote these tablets throughout the United States under the trade name "PROTONIX."

9. Upon information and belief, Altana is the owner of the United States Patent No. 4,758,579 ("the '579 patent"), which purports to claim pantoprazole sodium, and United States Patent No. 5,997,903 ("the '903 patent"), which purports to claim tablets containing pantoprazole sodium as the active compound.

10. Upon information and belief, Wyeth is the exclusive licensee of the '579 and '903 patents in the United States.

11. Copies of the '579 and '903 patents are attached hereto as Exhibits A and B.

12. On February 2, 2004, Sun filed ANDA No. 77-058 with the U.S. Food and Drug Administration seeking approval to market pantoprazole sodium delayed-release tablets, eq. to 20 mg and 40 mg base, in the United States.

13. On May 5, 2004, Sun sent a notice letter to each of Wyeth and Altana. Upon information and belief, Altana received the notice letter on or about May 13, 2004, and Wyeth received it on or about May 7, 2004. Said notice letter informed Altana and Wyeth that Sun's ANDA No. 77-058 contains a certification that, in the opinion of Sun and to the best of its knowledge, the '903 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's pantoprazole sodium delayed-release tablets which are the subject of Sun's ANDA No. 77-058.

14. On March 1, 2005, Sun sent a second notice letter to each of Altana and Wyeth which second notice letter, upon information and belief, was received by Altana on or about March 8, 2005, and by Wyeth on March 4, 2005. Said second notice letter informed Altana and Wyeth that, in the opinion of Sun and to the best of its knowledge, the '579 patent is invalid,

unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's pantoprazole sodium delayed release tablets which are the subject of Sun's ANDA No. 77-058.

15. On or about April 13, 2005, Altana and Wyeth filed or caused to be filed a Complaint in this District for patent infringement which alleges that Sun infringes the '579 patent. Said Complaint contains no allegations of infringement of the '903 patent.

16. On or about March 30, 2005, attorneys for Sun requested Altana and Wyeth to enter into a covenant not to sue Sun for infringement of the '903 patent.

17. On or about March 31, 2005, Altana and Wyeth, through their attorneys, refused to enter into a covenant not to sue Sun for infringement of the '903 patent.

18. On or about May 5, 2005, Sun filed or caused to be filed an Answer with Affirmative Defenses and Counterclaims in response to Altana and Wyeth's Complaint, requesting, inter alia, that said Complaint be dismissed and that the '579 patent be declared invalid.

19. There is an actual, substantial, and continuing justifiable controversy between Sun and Defendants regarding the infringement, validity, and enforceability of the '903 patent.

COUNT I

INVALIDITY OF THE '903 PATENT

20. Sun realleges all of the allegations in paragraphs 1 through 19 above as if set forth here.

21. The claims of the '903 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

22. Sun is entitled to a declaration that all of the claims of the '903 patent are invalid, void and/or unenforceable.

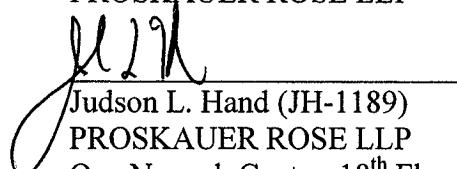
PRAYER FOR RELIEF

WHEREFORE, Sun prays that the Court enter:

- A. A declaratory judgment that the '903 patent is invalid;
- B. An Order enjoining and restraining Altana and Wyeth, and their respective officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them, from further charges of infringement or acts of enforcement based on the '903 patent against Sun, its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Sun; and
- C. An Order awarding Sun such other further relief as the Court deems just and equitable.

Dated: May 5, 2005

PROSKAUER ROSE LLP


Judson L. Hand (JH-1189)
PROSKAUER ROSE LLP
One Newark Center, 18th Floor
Newark, NJ 07102
973-274-3200

Charles Guttman
James H. Shalek
PROSKAUER ROSE LLP
1585 Broadway
New York, New York 10036
(212) 969-3000

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceuticals Advanced
Research Centre